

- 8 d) flowing the lysed cell solution and the precipitation solution through a
9 second static mixer, thereby forming a precipitation mixture;
- 10 e) centrifuging the precipitation mixture, thereby forming a pellet and a
11 clarified solution comprising the plasmid DNA; and
- 12 f) neutralizing either the precipitation mixture prior to the centrifugation of
13 step (e) or the clarified solution following the centrifugation of step (e);
- 14 g) contacting the clarified solution with a positively charged ion exchange
15 chromatography resin, wherein the plasmid DNA is eluted from the ion exchange
16 chromatography resin with a saline step or continuous gradient; and
- 17 h) filtering the clarified solution of step (f) through an ultrafiltration unit
18 comprising a gel layer either before or after contacting the clarified solution with the positively
19 charged ion exchange resin of step (g), thereby producing a solution of plasmid DNA of
20 sufficient purity and quantity for pharmaceutical use, wherein the solution comprises at least
21 about 100 mg of the plasmid DNA.

REMARKS

STATUS

Claims 1-21 are pending in this application, no claims being amended or canceled and claim 21 being added herein. Support for this new claim 21 can be found in the currently pending claim 1 and in the specification at least on page 11, line 22 - page 16, line 18. This amendment introduces no new matter.

Claims 17-19 were rejected under the judicially created doctrine of obviousness type double patenting as allegedly obvious over claims 1-62 of U.S. Patent No. 6,011,148.

Claims 1-17 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 96/02658 in view of U.S. Patent No. 5,837,529 and Maniatis, T. (both of record). Claims 1-20 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 96/02658 in view of U.S. Patent No. 5,837,529 and Maniatis, T. and further in view of U.S. Patent Nos. 5,256,294 and 5,034,314.

Applicants respectfully traverse these rejections. A petition to extend the period of response for three months is enclosed. A copy of the currently pending claims after entry of this Amendment is provided as Appendix I for the Examiner's convenience.